MDHHS
Michigan Department of Health & Human Services

COVID-19 Vaccine Update
MDHHS TB Program

January 20, 2021

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Topics Covered

- mRNA Vaccines
- Vaccine Efficacy and Safety
- Clinical Considerations for COVID-19 Vaccines
  - Recommendations for Use (Including TB Populations)
  - Administration points
  - Contraindications and Precautions
- What to Expect and Side Effects
- Adverse Events
- COVID-19 Resources
- Any questions

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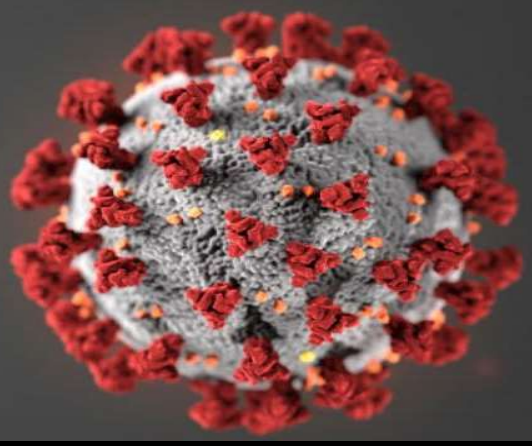
Vaccine Development Process and Ensuring Safety



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mRNA COVID-19 Vaccines Authorized for EUA

- Two COVID-19 vaccines have been authorized for use by the FDA under an Emergency Use Authorization (EUA)
  - **Pfizer BioNTech** COVID-19 Vaccine
    - For persons 16 years of age and older
    - 2 doses 21 days apart with 95% efficacy after 2nd dose
  - **Moderna** COVID-19 Vaccine
    - For persons 18 years of age and older
    - 2 doses 28 days apart with 94.1% efficacy after 2nd dose
- Patients should be counseled on importance of completing the 2-dose series in order to optimize protection

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Explaining mRNA COVID-19 Vaccines

- mRNA vaccines take advantage of the process that cells use to make proteins in order to trigger an immune response
  - Like all vaccines, COVID-19 mRNA vaccines have been **rigorously tested** for safety before being authorized for use in the United States
  - mRNA technology is **new, but not unknown**
    - They have been studied for more than a decade
  - mRNA vaccines **do not contain live virus** and do not carry a risk of causing disease in the vaccinated person
  - mRNA from the vaccine never enters the nucleus of the cell and **does not affect or interact with a person's DNA**

Source: Understanding and Explaining mRNA COVID-19 Vaccines | CDC

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COVID-19 Vaccines Under Development

- There are over 200 COVID-19 vaccines currently under development
- The federal government is funding and coordinating the development of multiple vaccine candidates
  - 2 vaccines have already received recommendations for use under an Emergency Use Authorization (EUA)
- COVID-19 vaccines are being held to the **same safety standards** as all other vaccines

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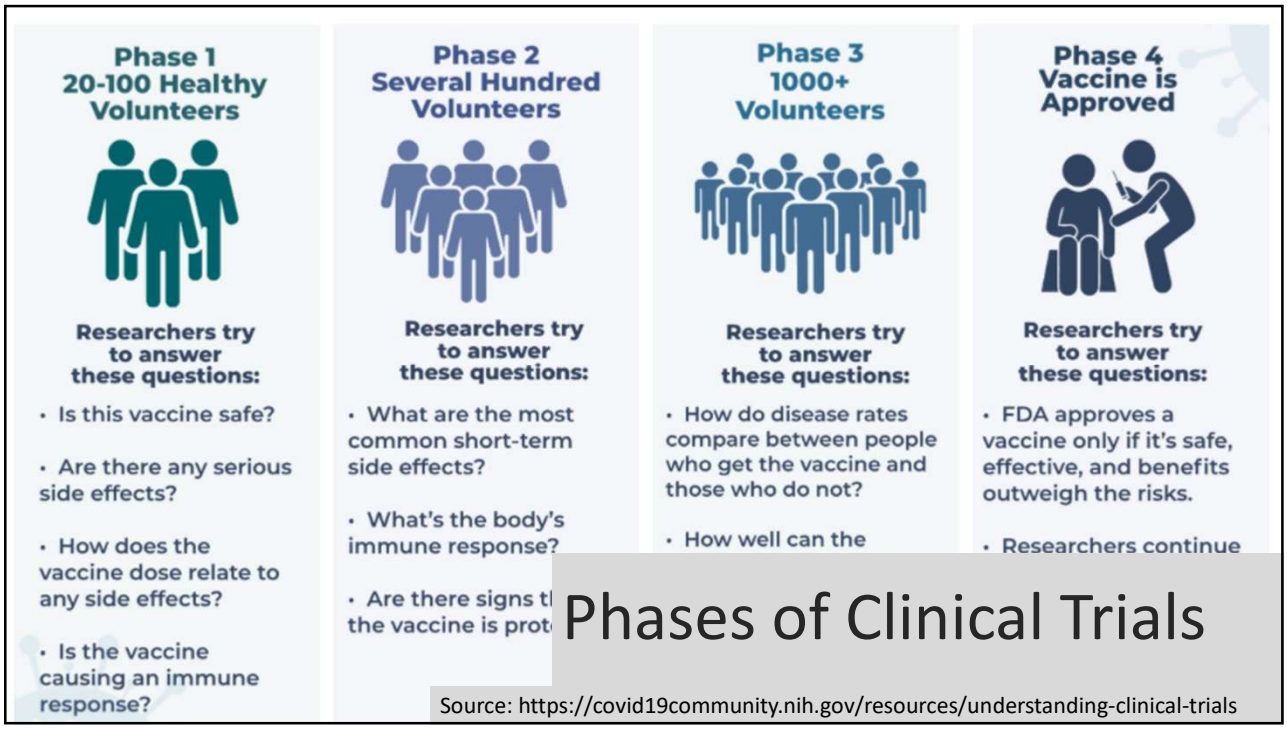

Phases of Clinical Trials

Source: https://covid19community.nih.gov/resources/understanding-clinical-trials

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Safety of COVID-19 Vaccines

- COVID-19 vaccines are being held to the **same safety standards** as all vaccines
- The U.S. vaccine safety system ensures that all vaccines are as safe as possible
- Safety is the top priority

Before authorization
- **FDA** carefully reviews all safety data from clinical trials.
- **ACIP** reviews all safety data before recommending use.

After vaccine authorization
- **FDA** and **CDC** closely monitor vaccine safety and side effects.

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Q: How Was the Vaccine Development Timeline Accelerated While Ensuring Safety?

- Researchers used existing clinical trial networks to begin conducting COVID-19 vaccine trials*
- Manufacturing started while the clinical trials were still underway. Normally, manufacturing doesn't begin until after completion of the trials
  - Normally, manufacturing doesn’t begin until after completion of the trials
- mRNA vaccines are faster to produce than traditional vaccines
  - The new COVID-19 vaccines have been evaluated in tens of thousands of individuals, who volunteered to be vaccinated and to participate in clinical trials
    - To make sure they meet safety standards and protect adults of different ages, races, and ethnicities
  - There were no serious safety concerns
  - CDC and the FDA will keep monitoring the vaccines to look for safety issues after they are authorized and in use.

*For more information, visit the COVID-19 Prevention Network: www.coronaviruspreventionnetwork.org/about-covpn

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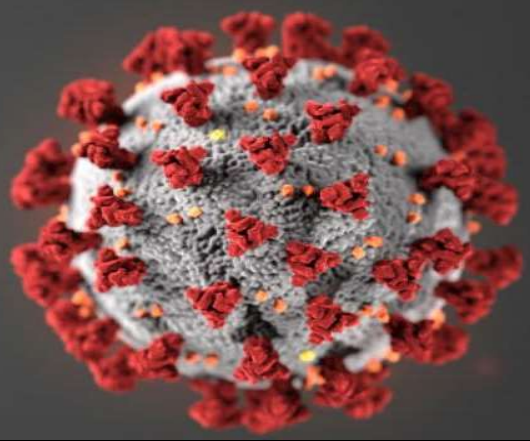
mRNA Vaccines (Moderna and Pfizer-BioNTech)



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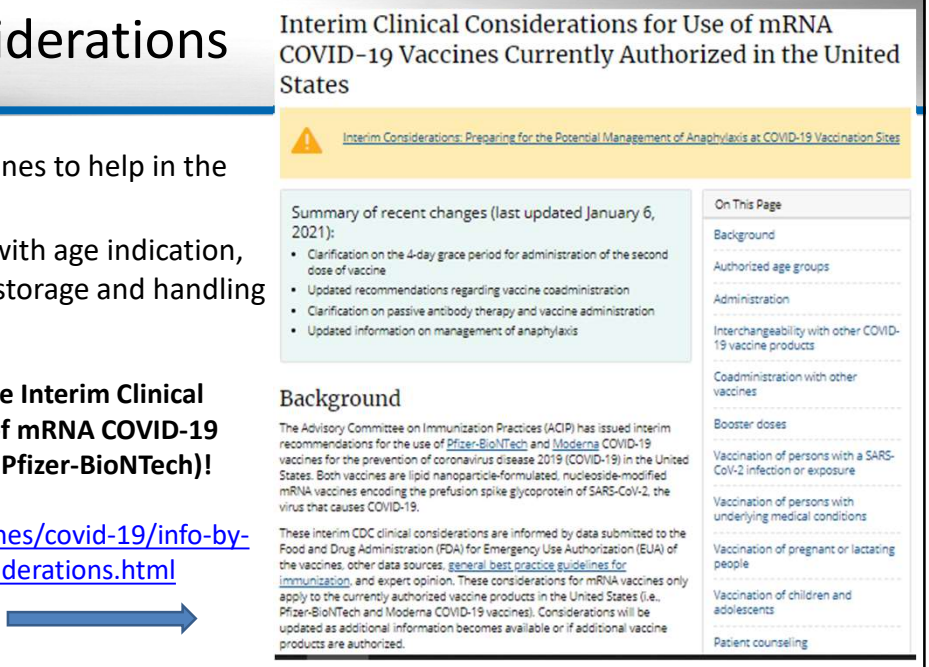
Clinical Considerations

- We have 2 mRNA vaccines to help in the fight against COVID-19
- There are differences with age indication, dosing, schedule, and storage and handling

Updated website for the Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines (Moderna and Pfizer-BioNTech)!

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html



Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States

Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites

Summary of recent changes (last updated January 6, 2021):
- Clarification on the 4-day grace period for administration of the second dose of vaccine
- Updated recommendations regarding vaccine coadministration
- Clarification on passive antibody therapy and vaccine administration
- Updated information on management of anaphylaxis

On This Page
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Coadministration with other vaccines
Booster doses
Vaccination of persons with a SARS-CoV-2 infection or exposure
Vaccination of persons with underlying medical conditions
Vaccination of pregnant or lactating people
Vaccination of children and adolescents
Patient counseling

Background

The Advisory Committee on Immunization Practices (ACIP) has issued interim recommendations for the use of Pfizer-BioNTech and Moderna COVID-19 vaccines for the prevention of coronavirus disease 2019 (COVID-19) in the United States. Both vaccines are lipid nanoparticle-formulated, nucleoside-modified mRNA vaccines encoding the prefusion spike glycoprotein of SARS-CoV-2, the virus that causes COVID-19.

These interim CDC clinical considerations are informed by data submitted to the Food and Drug Administration (FDA) for Emergency Use Authorization (EUA) of the vaccines, other data sources, general best practice guidelines for immunization, and expert opinion. These considerations for mRNA vaccines only apply to the currently authorized vaccine products in the United States (i.e., Pfizer-BioNTech and Moderna COVID-19 vaccines). Considerations will be updated as additional information becomes available or if additional vaccine products are authorized.

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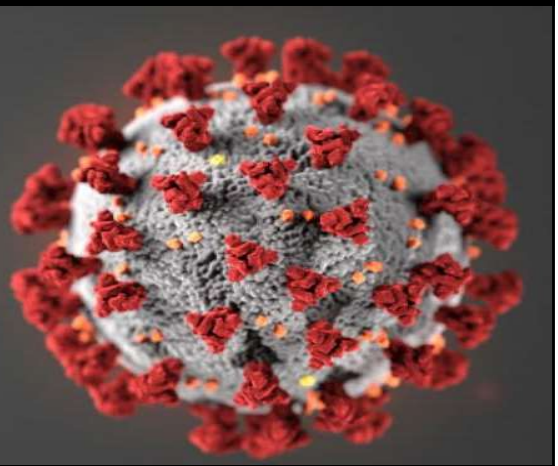
Recommendations for Use of mRNA Vaccines (Moderna and Pfizer-BioNTech) In Different Populations



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The Clinical Considerations for mRNA Vaccines

- Reviews considerations for vaccination of special populations:
  - Persons with **prior** SARS-CoV-2 infection
  - Persons with known **current** SARS-CoV-2 infection
  - Persons who **previously received p**assive antibody therapy for COVID-19
  - Persons with underlying medical conditions
  - Immunocompromised persons
  - Pregnant or lactating people

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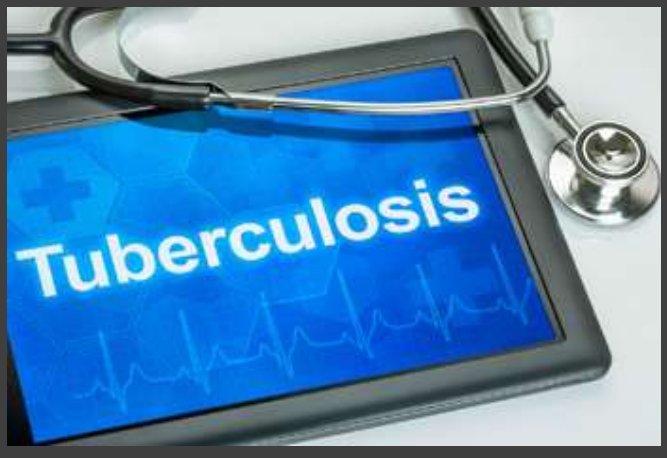
Tuberculosis Test in Vaccinated Persons



- Inactive vaccines do not interfere with tuberculosis (TB) test results
- There is no immunologic reason to believe either a Tuberculin Skin Test (TST) or blood draw for interferon gamma release assay (IGRA) would affect the safety or effectiveness of mRNA COVID-19 vaccines
- We have no data to inform the impact of the COVID-19 mRNA vaccines on either TB test for infection (i.e., TST or IGRA)

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

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Tuberculosis Test in Vaccinated Persons cont……

- For healthcare personnel or patients who require baseline TB testing (at onboarding or entry into facilities) at the same time they are to receive an mRNA COVID-19 vaccine:
  - Perform TB symptom screening on all healthcare personnel or patients
  - If utilizing the IGRA, draw blood for interferon gamma release assay prior to COVID-19 vaccination
  - If utilizing the TST, place prior to COVID-19 vaccination
  - If vaccination has been given and testing needs to be performed, defer TST or IGRA until 4 weeks after COVID-19 vaccine 2-dose completion
    - All potential recipients of COVID-19 vaccination should weigh the risks and benefits of delaying TST/IGRA with their providers

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Tuberculosis Test in Vaccinated Persons cont. (2)

- For healthcare personnel who require testing for other reasons:
  - Perform TB symptom screening on all healthcare personnel
  - Test for infection should be done before or at the same time as the administration of COVID-19 vaccination
    - Healthcare personnel with high-risk conditions for TB progression should be fully evaluated as soon as possible
    - Healthcare personnel without high-risk conditions for TB progression should proceed with contact investigation (i.e., symptom screening, chest radiograph or other imaging, specimen for microbiologic evaluation) but delay test for TB infection (TST or IGRA) if prioritized for receiving COVID-19 vaccination
    - All potential recipients of COVID-19 vaccination should weigh the risks and benefits of delaying TST/IGRA with their providers

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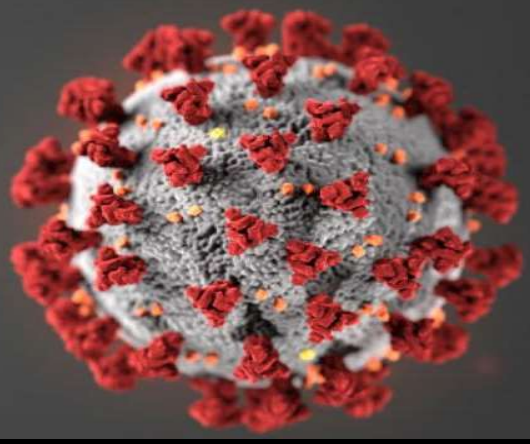
Additional Clinical Considerations for mRNA COVID-19 Vaccines



https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

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Interchangeability with Other COVID-19 Vaccines

- mRNA COVID-19 vaccines are not interchangeable with other COVID-19 vaccine products
  - Safety and efficacy of a mixed series has not been evaluated
- Persons initiating series should complete series with same product
- If two dose of different mRNA COVID-19 vaccine products are inadvertently administered, no additional doses of either vaccine is recommended at this time
  - Recommendations may be updated as further information becomes available or additional vaccine types are authorized

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Coadministration with Other Vaccines

- mRNA COVID-19 vaccines **should be administered alone** with a minimum interval of 14 days before or after administration of any other vaccines
  - Due to lack of data on safety and efficacy of the vaccine administered simultaneously with other vaccines
- mRNA COVID-19 and other vaccines may be administered within a shorter period in situations where the benefits of vaccination are deemed to outweigh the potential unknown risks of vaccine coadministration (e.g., tetanus toxoid-containing vaccination as part of wound management)
- If a mRNA COVID-19 vaccine is administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine

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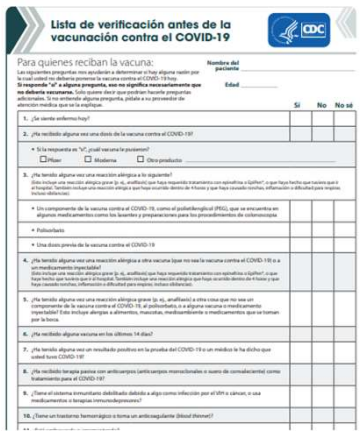
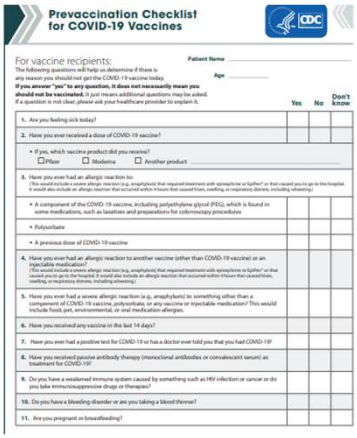
Tools to Identify Persons with Contraindications and Precautions


Lista de verificación antes de la vacunación contra el COVID-19

Para quienes reciban la vacuna:


Prevaccination Checklist for COVID-19 Vaccines

For vaccine recipients:

Pfizer-BioNTech COVID-19 Vaccine Prevaccination Checklist (English and Spanish):

- https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html

Moderna COVID-19 Vaccine Prevaccination Checklist (English and Spanish):

- https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html

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Algorithm for the triage of persons presenting for mRNA COVID-19 vaccine

	MAY PROCEED WITH VACCINATION	PRECAUTION TO VACCINATION	CONTRAINDICATION TO VACCINATION
CONDITIONS	**CONDITIONS** • Immunocompromising conditions • Pregnancy • Lactation **ACTIONS** • Additional information provided* • 15 minute observation period	**CONDITIONS** • Moderate/severe acute illness **ACTIONS** • Risk assessment • Potential deferral of vaccination • 15 minute observation period if vaccinated	**CONDITIONS** • None **ACTIONS** • N/A
ALLERGIES	**ALLERGIES** • History of food, pet, insect, venom, environmental, latex, or other allergies not related to vaccines or injectable therapies • History of allergy to oral medications (including the oral equivalent of an injectable medication) • Non-serious allergy to vaccines or other injectables (e.g., no anaphylaxis) • Family history of anaphylaxis • Any other history of anaphylaxis that is not related to a vaccine or injectable therapy **ACTIONS** • 30 minute observation period: Persons with a history of severe allergic reaction (e.g., anaphylaxis) due to any cause • 15 minute observation period: Persons with allergic reaction, but not anaphylaxis	**ALLERGIES** • History of severe allergic reaction (e.g., anaphylaxis) to another vaccine (not including mRNA COVID-19 vaccines†) • History of severe allergic reaction (e.g., anaphylaxis) to an injectable therapy **ACTIONS:** • Risk assessment • Potential deferral of vaccination • 30 minute observation period if vaccinated	**ALLERGIES** • History of severe allergic reaction (e.g., anaphylaxis) to any component of an mRNA COVID-19 vaccine† **ACTIONS** • Do not vaccinate

Chart available at: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

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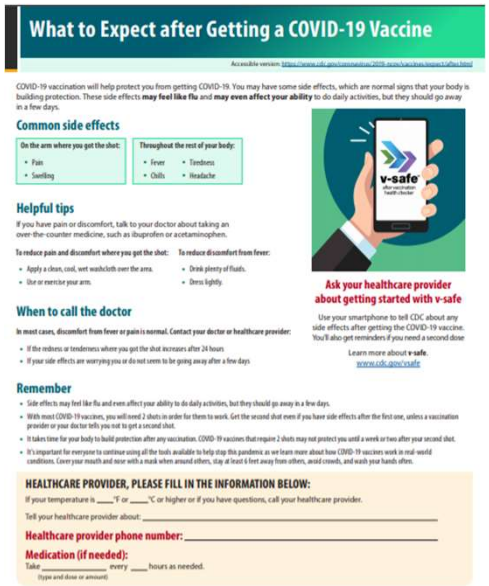
Reactogenicity

- Before vaccination, inform the vaccine recipients about expected local and systemic post-vaccination symptoms
- Unless a person develops a contraindication to vaccination, they should be encouraged to complete the series
- Antipyretic or analgesic medications may be taken for treatment of post-vaccination symptoms
  - Routine prophylaxis for the purposes of preventing symptoms is not recommended at this time, due to lack of information on impact of use on vaccine-induced antibody responses



What to Expect after Getting A COVID-19 Vaccine https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html

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VAERS Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

Adverse Event Reporting

- Required that the following AEs be reported to VAERS:
  - Vaccine administration errors (whether associated with an AE or not)
  - Serious AEs (irrespective of attribution to vaccination)
  - Multisystem Inflammatory Syndrome (MIS)
  - Cases of COVID-19 that result in hospitalization or death after the recipient has received COVID-19 vaccine
- Any clinically significant AEs that occurs after vaccine administration should also be reported to VAERS
- Information on how to submit a report to VAERS is available at https://vaers.hhs.gov/index.html or 1-800-822-7967

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Vaccine Safety Monitoring- V-Safe Text-based System for the Public

- Many existing systems will be used and enhanced for monitoring the safety of COVID-19 vaccines, e.g., Vaccine Adverse Events Reporting System (VAERS) and Vaccine Safety Datalink
- CDC is asking COVID-19 vaccine providers to encourage enrollment in v-safe when they get their first vaccine dose
  - Will provide prospective information on adverse events
- More information about V-safe can be found at: https://www.cdc.gov/vsafe

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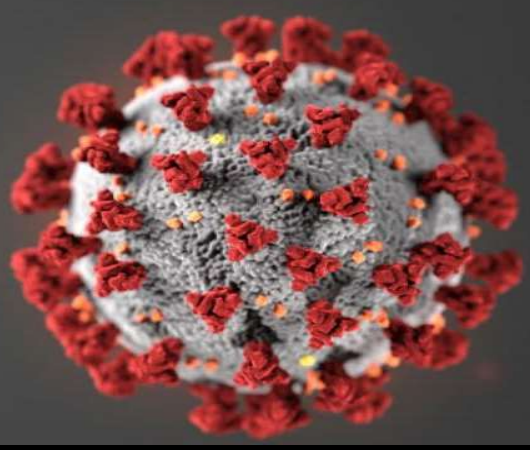
mRNA COVID-19 Vaccines (Moderna and Pfizer-BioNTech) Resources



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MDHHS COVID-19 Web Page
www.Michigan.gov/COVIDVaccine

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COVID-19 Vaccination

Clinical Resources for Each COVID-19 Vaccine

Find information for COVID-19 vaccination administration, storage and handing, reporting, and patient education for each specific vaccine

Product Information by US Vaccine

***CDC's **UPDATED** Web Page for COVID-19 Vaccination Education

- Links to several CDC pages such as the storage and handling toolkit, vaccine administration, ACIP recommendations, and more
- Links to the COVID-19 product vaccine information
- There is a "Vaccination Resource Toolkits" tab that reviews the Communication Toolkit
- For further information: https://www.cdc.gov/vaccines/covid-19/index.html

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CDC COVID-19 Vaccine Information for You and Your Family

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html

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Thank you
Any Questions Regarding
COVID-19 Vaccines and TB?

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